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| 09/485,187 | 06/26/2000 | Marion Kwart | 147-191P | 1628 |

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EXAMINER

KUBELIK, ANNE R

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| ART UNIT | PAPER NUMBER |
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1638

DATE MAILED: 04/10/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/485,187

Applicant(s)

KWART ET AL.

Examiner

Anne Kubelik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 4, 6 and 7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 1-3 and 8-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other

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DETAILED ACTION

1. Applicant's election with traverse of Group II (claims 1-3, 5 and 8-15, to the extent they read on sucrose transporters) in Paper No. 9 is acknowledged. The traversal is on the ground(s) that in a Lack of Unity requirement, "special technical features" refers to those technical features that define a contribution of each invention, considered as a whole, over the prior art. The special technical feature of the current invention is a method for increasing plant yield using a companion cell promoter and a gene encoding any of a number of proteins. Applicant argues that the method of increasing yield in Lerchl et al provides no information for an increase in biomass or yield. Applicant also argues that no unity of invention requirement was made in the International Phase of the application. Applicant also argues that the instant invention was not considered as a whole in the restriction requirement, and that the total combinations of all the inventions over the prior art is what should be considered.

This is not found persuasive because Lerchl et al teach a species of that special technical feature of a method for increasing plant yield using a companion cell promoter and a gene encoding any of a number of proteins. The recombinant DNA molecule made by Lerchl et al would inherently produce plants with increased yield. Thus, the inventions as a whole are not an advance over the prior art. Furthermore, US examiners are not held to decisions made by European patent examiners to examine all groups.

Claims 4 and 6-7 are withdrawn from consideration. Claims 1-3, 5 and 8-15 are examined to the extent they read on sucrose transporters. Claims 1, 9 and 15 should be amended to delete non-elected enzymes.

The requirement is still deemed proper and is therefore made FINAL.

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2. The drawings are objected to for the reasons indicated on accompanying form PTO 948. Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.

Also note that in the convention of Patent Drawings, the A, B, C and D in Figures 5 and 8 should refer to parts of the figures (as done in Figure 2), and they require separate mention in the Figure legend (Figure 5A, Figure 5B, etc). The current usage is likely to result in problems at publication.

3. The disclosure is objected to because faint and irregular lettering would result in printing errors.

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and must be accompanied by: 1) a statement that the substitute specification contains no new matter; and 2) a marked-up copy showing the amendments to be made via the substitute specification relative to the specification at the time the substitute specification is filed.

4. The title of the invention is not descriptive of the instant invention. A new title is required that is clearly indicative of the invention to which the claims are directed. Note that titles can be up to 500 characters long.

5. The abstract is not descriptive of the instant invention. A new abstract is required that is clearly indicative of the invention to which the claims are directed.

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6. The information disclosure statement filed 11 January, 2002 (Paper No. 14) fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each publication listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Objections

7. Claim 14 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). For purposes of examination, claim 14 was treated as though it were solely dependent upon claim 13. Such treatment does not relieve Applicant of the responsibility to respond to this rejection.

8. Claim 8 is objected to for being dependent upon non-elected claims.

9. Claims 9 and 11 are objected to because of the following informalities:

The comma after "polypeptide" in claim 9, part (b), should be deleted.

The article before "transformation" in claim 11 should be deleted.

Claim Rejections - 35 USC § 101

10. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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11. Claim 15 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, *i.e.*, results in a claim that is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 1-3, 5 and 8-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a multitude of DNA molecules that comprise a companion cell specific promoter operably linked to a sucrose transporter gene and plants and plant cells transformed with those DNA molecules.

The instant specification only described a sucrose transporter gene from spinach (pg 3, last paragraph); EMBL Accession No.G21319, the other transporter cited, is actually a human sequence tagged site and is too short to encode a full-length sucrose transporter. The instant specification fails to describe a sucrose transporter gene from any plant other than spinach or

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from any bacterium or fungus. No description is provided as to sequence of any companion cell promoter other than the *rolC* promoter or the *Arabidopsis* sucrose transporter promoter (pg 5, paragraphs 2-3).

Hence, Applicant has not, in fact, described DNA molecules that comprise a companion cell specific promoter operably linked to a sucrose transporter gene within the full scope of the claims, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, it is not clear that Applicant was in possession of the genus claimed at the time this application was filed.

See *Univ. Calif. v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997), pg 1406:

a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the genes does, not what it is.

See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at page 1021:

A gene is a chemical compound, albeit a complex one, and ... conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials.... Conception does not occur unless one has a mental picture of the structure of the chemical or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, *e.g.*, encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

See *In re Shokal*, 113 USPQ 283, (CCPA 1957) at pg 285

It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. *In re Soll*, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; *In re Wahlforss et al.*, 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix

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any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary. ...

We are of the opinion that a genus containing such a large number of species cannot properly be identified by the mere recitation or reduction to practice of four or five of them. As was pointed out by the examiner, four species might be held to support a genus, if such genus is disclosed in clear language; but where those species must be relied on not only to illustrate the genus but to define what it is, the situation is otherwise.

14. Claims 1-3, 5 and 8-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of increasing the yield of plants by transformation with a construct comprising the *rolC* promoter operably linked to the sucrose transporter gene from spinach, does not reasonably provide enablement for such a method by transformation with any companion cell specific promoter or any sucrose transporter gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to a method for increasing the yield of plants by transforming the plants with a sucrose transporter gene from any source expressed behind any companion-cell specific promoter, constructs used in that method, and plants so obtained.

The instant specification, however, only provides guidance for a sucrose transporter gene from spinach (pg 3, last paragraph) and the *rolC'* and the *Arabidopsis* sucrose transporter promoter (pg 5, paragraphs 2-3). The instant specification also provides guidance for *Agrobacterium*-mediated transformation of potato with a construct comprising the *rolC'* promoter operably linked to spinach sucrose transporter gene and production of plants with increased biomass (example 5).

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The instant specification fails to provide guidance for sucrose transporter genes from other sources, including other plants or bacteria or fungi. The instant specification fails to provide guidance for other companion cell specific promoters.

Isolation of a gene is unpredictable, given the lack of guidance provided by the specification with respect to the sequences of the probes and primers to be used, the hybridization and wash conditions, and PCR reaction conditions. Thus, undue experimentation would be required to screen through a myriad of clones to isolate other nucleic acids encoding sucrose transporters that are structurally related to unrelated to the spinach nucleic acid.

One of the "sucrose transporter genes" described in the specification (EMBL Accession No.G21319) is actually a human sequence tagged site and is too short to encode a full-length sucrose transporter. The instant specification fails to describe how such a sequence could be used to increase yield in a plant.

Given the claim breath and lack of guidance in the specification as discussed above, the instant invention is not enabled throughout the full scope of the claims.

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

16. Claims 1-3, 5 and 8-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claims 1-3, 5 and 8 are indefinite because they fail to recite positive method steps and because they lack agreement between the preamble of the methods and the positive method

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steps. A claim must set forth active, positive steps involved in the method/process delimiting how this use is actually practiced. Each step must start with a verb in gerund form (*e.g.*, A method for increasing the yield of plants, comprising **transforming** a plant with a DNA construct comprising ...). Methods must also be circular; the final step must generate the item the method is intended to produce. For example, the method of increasing the yield in a plant in claim 1 ends in expressing a nucleic acid, when it should end in the production plants with increased yield.

Claims 1, 9-10, 12-13 and 15 are indefinite in their recitation of the word "containing" and claim 14 is indefinite in its recitation of "contains". It is unclear if these words are intended to be open or closed. If open language is intended, the words should be replaced with --comprising-- and --comprises--, respectively.

Claim 9 is indefinite in its recitation of "yields". It is not clear which yields are being referred to. It is also not clear if Applicant intends that all possible yields of the plant be increased at the same time.

In claim 11, "which" should be replaced with --, wherein the vector--.

Claim 15 provides for the use of a recombinant nucleic acid molecule, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

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Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a), which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. Claims 1-2, 5 and 8-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frommer et al (1997, US Patent 5,608,146) in view of Kuhn et al (1996, Plant Cell Environ. 19:1115-1123).

The claims are drawn to a method for increasing the yield of plants by transforming the plants with a sucrose transporter gene expressed behind a companion-cell specific promoter, constructs used in that method and plants so obtained.

Frommer et al disclose tobacco plants transformed with construct comprising a sucrose transporter gene from spinach expressed behind a constitutive promoter (column 17, line 49, to column 18, line 32). Frommer et al teach that such plants have increased yield (column 11, lines 18-30). Frommer et al do not disclose plants transformed with a sucrose transporter gene expressed behind a companion-cell specific promoter.

Kuhn et al teach potato plants transformed with a DNA construct comprising the companion cell-specific *rolC'* promoter operably linked to the potato *SUT1* sucrose transporter in the antisense orientation (pg 1116, left column, paragraphs 2-3, and pg 1117, left column, paragraph 2).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of increasing the yield of plants by transforming with a spinach

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sucrose transporter as taught by Frommer et al, to substitute the rolC promoter as described in Kuhn et al for the constitutive promoter in order to express the sucrose transporter in companion cells. One of ordinary skill in the art would have been motivated to do so because Kuhn et al teach that plants transformed with antisense SUT1 expressed behind a companion cell promoter have reduced tuber yield (paragraph spanning the columns, pg 1117); one of skill in the art would know that overexpression would have the opposite effect. Also, Frommer et al teach that an improvement in the delivery of storage substances to storage tissue increases yield (column 11, lines 18-30); expression in companion cells would focus that delivery.

19. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Frommer et al in view of Kuhn et al as applied to claims 1-2, 5 and 8-15 above, and further in view of Leggewie et al (US Patent 6,025,544, 102(e) date July, 1997).

The claims are drawn to a method for increasing the yield of plants by transforming the plants with a sucrose transporter gene from bacteria expressed behind a companion-cell specific promoter.

Frommer et al in view of Kuhn et al disclose a method for increasing the yield of plants by transforming the plants with a sucrose transporter gene expressed behind a companion-cell specific promoter, constructs used in that method and plants so obtained. Frommer et al in view of Kuhn et al do not disclose plants transformed with a sucrose transporter gene from bacteria.

Leggewie et al teach a method of transforming plants with a DNA construct comprising a promoter operably linked to a bacterial sucrose transporter (claims 12-15).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method for increasing the yield of plants by transforming the plants with

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a sucrose transporter gene expressed behind a companion-cell specific promoter, as taught by Frommer et al in view of Kuhn et al, to substitute a sucrose transporter gene from bacteria, as described in Leggewie et al for the spinach sucrose transporter gene. One of ordinary skill in the art would have been motivated to do so because the two genes are functional equivalents, and it would have been obvious to substitute one functional equivalent for another.

Conclusion

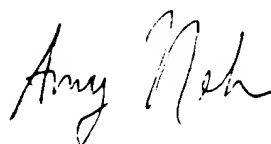
20. No claim is allowed.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Kimberly Davis, at (703) 305-3015.

Anne R. Kubelik, Ph.D.
April 8, 2002



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